



Docket No. AZ-0020

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Yam et al.

Serial No. : 10/629,211

Confirmation No.: 5309

Filed : July 28, 2003

For : METHODS AND DOSAGE FORMS FOR CONTROLLED DELIVERY
OF PALIPERIDONE

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope addressed
to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

April 15, 2004

(Date of Deposit)

Laura A. Donnelly

(Name of applicant, assignee, or Registered Representative)

(Signature)

April 15, 2004

(Date of Signature)

MAIL STOP DD
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e)
(attached); or

☐ Please charge Deposit Account No. 10-
0750/ / the fee of \$180.00 as set forth
in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e)
(attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the

national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

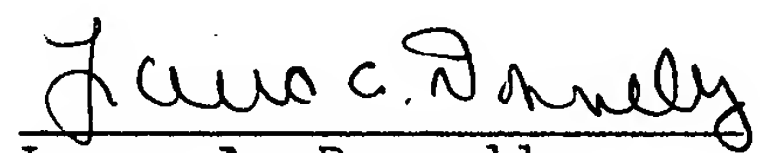
☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/AZ-0020/LAD. This form is submitted in triplicate.

Respectfully submitted,


Laura A. Donnelly
Reg. No. 38,435
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1729
DATED: April 15, 2004



Substitute for form 1449A-PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Application Number	10/629,211
Filing Date	July 28, 2003
First Named Inventor	Noymi YAM
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	AZ0020USANP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
	AA	2002/0051807	A1	FAOUR et al.	05-02-2002	
	AB	2002/0035357	A1	FAOUR et al.	03-21-2002	
	AC	2001/0012847	A1	LAM et al.	08-09-2001	
	AD	6,368,632	B1	MESENS et al.	04-09-2002	
	AE	6,110,923		ELY	08-29-2000	
	AF	5,965,168		MESENS et al.	10-12-1999	
	AG	5,871,778		KINO et al.	02-16-1999	
	AH	5,770,843	A, X6	ROSE et al.	06-23-1998	
	AI	5,770,231		MESENS et al.	06-23-1998	
	AJ	5,692,477		BERGER et al.	12-02-1997	
	AK	5,656,299		KINO et al.	08-12-1997	
	AL	5,654,008		HERBERT et al.	08-05-1997	
	AM	5,650,173		RAMSTOCK et al.	07-22-1997	
	AN	5,633,011		DONG et al.	05-27-1997	
	AO	5,620,705		DONG et al.	04-15-1997	
	AP	5,536,507		ABRAMOWITZ et al.	07-16-1996	
	AQ	5,252,338		JAO et al.	10-12-1993	
	AR	5,190,765		JAO et al.	03-02-1993	
	AS	5,169,638		MATSUI et al.	12-08-1992	
	AT	5,160,743		EDGREN et al.	11-03-1992	
	AU	5,156,850		WONG et al.	10-20-1992	
	AV	5,126,142		AYER et al.	06-30-1992	
	AW	5,024,842		EDGREN et al.	06-18-1991	
	AX	5,019,397		WONG et al.	05-28-1991	
	AY	5,006,346		EDGREN et al.	04-09-1991	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 4

<i>Application Number</i>	10/629,211
<i>Filing Date</i>	July 28, 2003
<i>First Named Inventor</i>	Noymi YAM
<i>Group Art Unit</i>	Not yet assigned
<i>Examiner Name</i>	Not yet assigned
<i>Attorney Docket Number</i>	AZ0020USANP

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Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
	AZ	4,940,465		THEEUWES et al.	07-10-1990	
	BA	4,931,285		EDGREN et al.	06-05-1990	
	BB	4,915,949		WONG et al.	04-10-1990	
	BC	4,892,778		THEEUWES et al.	01-09-1990	
	BD	4,804,663	A, X6	KENNIS et al.	02-14-1989	
	BE	4,681,583		URQUHART et al.	07-21-1987	
	BF	4,578,075		URQUHART et al.	03-07-1978	
	BG	4,519,801		EDGREN	05-28-1985	
	BH	4,458,076	A, X6	STRUPCZEWSKI et al.	07-03-1984	
	BI	4,352,811	A, X6	STRUPCZEWSKI et al.	10-05-1982	
	BJ	4,327,725		CORTESE et al.	05-04-1982	
	BK	4,207,893		MICHAELS	06-17-1980	
	BL	4,160,020		AYER et al.	07-03-1979	
	BM	4,111,202		THEEUWES	09-05-1978	
	BN	4,088,864		THEEUWES	05-09-1978	
	BO	4,077,407		THEEUWES et al.	03-07-1978	
	BP	4,008,719		THEEUWES et al.	02-22-1977	
	BQ	4,002,173		MANNING et al.	01-11-1977	
	BR	3,995,631		HIGUCHI	12-07-1976	
	BS	3,916,899		THEEUWES et al.	11-04-1975	
	BT	3,865,108		HARTOP	02-11-1975	
	BU	3,845,770		THEEUWES et al.	11-05-1974	

Examiner Signature		Date Considered	
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¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 4

Application Number 10/629,211

Filing Date July 28, 2003

First Named Inventor Noymi YAM

Group Art Unit Not yet assigned

Examiner Name Not yet assigned

Attorney Docket Number AZ0020USANP

U.S. PATENT DOCUMENTS

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		Number	Kind Code ² (if known)			
	BV	3,598,123		ZAFFORONI et al.	08-10-1971	
	BW	3,598,122		ZAFFORONI et al.	08-10-1971	
	BX	3,546,142		MICHAELS et al.	12-08-1970	
	BY	3,541,006		BIXLER et al.	11-17-1970	
	BZ	3,541,005		STRATHMANN et al.	11-17-1970	
	CA	3,276,586		ROSEAN	10-04-1966	
	CB	3,173,876		JACKSON	03-16-1965	
	CC	3,133,132		LOEB et al.	05-12-1964	
	CD	2,799,241		WURSTER	07-16-1957	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				
	CE	WO	01/52819	A1	LABORATORIOS PHOENIX U.S.A., Inc.	07-26-2001		
	CF	WO	01/37813	A2, 3	LTS LOHMANN THERAPIE-SYSTEME AG	05-31-2001		
	CG	WO	01/34120	A1	ALKERMES CONTROLLED THERAPEUTICS Inc.	05-17-2001		
	CH	WO	00/35419	A2	ALZA Corporation	06-22-2000		
	CI	WO	99/62496	A1	ALZA Corporation	12-09-1999		
	CJ	WO	98/23263	A1	ALZA Corporation	06-04-1998		
	CK	WO	98/14168	A2,A3	ALZA Corporation	04-09-1998		
	CL	WO	98/06380	A2,A3	ALZA Corporation	02-19-1998		
	CM	WO	97/44039	A1	JANSSEN PHARMACEUTICA N.V.	11-27-1997		
	CN	WO	96/31201	A1	JANSSEN PHARMACEUTICA N.V.	02-19-1998		

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SignatureDate
Considered

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4 of 4

<i>Application Number</i>	10/629,211
<i>Filing Date</i>	July 28, 2003
<i>First Named Inventor</i>	Noymi YAM
<i>Group Art Unit</i>	Not yet assigned
<i>Examiner Name</i>	Not yet assigned
<i>Attorney Docket Number</i>	AZ0020USANP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T ²
	CO	<u>Encyclopedia of Polymer Science and Technology</u> , 3:325-354, Interscience Publishers, NY, 1964. "Cellulose Esters, Organic"	
	CP	HIXON, Larry et al., <u>Chemical Engineering</u> , 94-103, November 1990. "Sizing Materials by Crushing and Grinding"	
	CQ	LEA & FEBINGER, <u>Biopharmaceutics and Pharmacokinetics</u> , 3 rd Ed., Ch1., pp. 1-28, 1984. "Introduction to Pharmacokinetics"	
	CR	LONGER, Mark A. et al., <u>Remington's Pharmaceutical Sciences</u> , 18 th Ed, Ch 91, pp.1676-1693, 1990. "Sustained-Release Drug Delivery Systems: Oral Dosage Forms"	
	CS	PARROTT, Eugene L., <u>Journal of Pharmaceutical Sciences</u> , 61(6):813-829, 1974. "Milling of Pharmaceutical Solids"	
	CT	<u>Perry's Chemical Engineers Handbook</u> , Perry, Green & Maloney Editors, et al, 6 th Ed., "Introduction to Screening and Wet Classification", pp. 21.13 to 21.19, 1984..	
	CU	<u>Physician's Desk Reference</u> , Thompson Healthcare, 56 th Ed., pp. 1796-1800, 2002. "Risperdal ®"	
	CV	<u>Physician's Desk Reference</u> , Thompson Healthcare, 56 th Ed., pp. 1998-2001, 2002. "Concerta ®"	
	CW	RIPPLE, Edward G., <u>Remington's Pharmaceutical Sciences</u> , 17 th Ed, Ch. 89, pp. 1585-1594, 1985. "Powders"	
	CX	SANTUS, Giancarlo & Richard W. Baker, <u>Journal of Controlled Release</u> , 35:1-21, 1995. "Osmotic drug delivery: a review of the patent literature"	
	CY	SCOTT & ROFF, <u>Handbook of Common Polymers</u> , CRC Press., Cleveland Ohio, 1971.	
	CZ	WURSTER, Dale E., <u>J. Am. Pharm. Assoc</u> , 48(8):451-454, August 1959. "Air-Suspension Technique of Coating Drug Particles"	
	DA	WURSTER, Dale E., <u>J. Am. Pharm. Assoc</u> , 49(2):82-84, February 1960. "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II"	

Examiner Signature		Date Considered	
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SUBMISSION UNDER MPEP 609 D Page 1 of 1	<i>Application Number</i>	10/629,211
	<i>Filing Date</i>	July 28, 2003
	<i>First Named Inventor</i>	Noymi YAM
	<i>Group Art Unit</i>	To be assigned
	<i>Examiner Name</i>	To be assigned
	<i>Attorney Docket Number</i>	AZ0020USANP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code ² (if known)	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
			Office ³	Number ⁴	KindCode ⁵		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		International Search Report dated December 17, 2003, for corresponding Appln No. PCT/US03/23433.	

Examiner Signature		Date Considered	
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Serial No. 10/629,211 Docket No. A2-0020 By: LRS
Application of: Yam et al. Mailed: April 15, 2004
Entitled: Methods and Dosage Forms for Controlled
Delivery of Saliperedone
THE FOLLOWING HAS BEEN RECEIVED IN THE U.S. PATENT OFFICE ON THE DATE STAMPED HEREON:

- | | |
|---|---|
| <input type="checkbox"/> Oath or Declaration | <input checked="" type="checkbox"/> MPEP 609/ <u>4</u> |
| <input type="checkbox"/> Assignment | <input type="checkbox"/> Notice of Appeal |
| <input checked="" type="checkbox"/> Charge to Deposit Account 10-0750 | <input type="checkbox"/> Brief |
| <input type="checkbox"/> Amendment | <input type="checkbox"/> Priority Document |
| <input type="checkbox"/> Extension of Time | <input type="checkbox"/> Status Inquiry |
| <input type="checkbox"/> Issue Fee Transmittal | <input type="checkbox"/> Sequence Listings/Diskette |
| <input type="checkbox"/> PCT Filing | <input type="checkbox"/> Biological Deposit Declaration |
| <input checked="" type="checkbox"/> IDS-Form 1449 | <input type="checkbox"/> Other |
| <input type="checkbox"/> Drawings <u> </u> sheets | |